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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,381	03/19/2004	Scott Edward Osborne	7892C	7237

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THE PROCTER & GAMBLE COMPANY
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EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,381

Applicant(s)

OSBORNE ET AL.

Examiner

Lakshmi S. Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of 2-3-05 is acknowledged.

Claims 1-20 are pending in the instant application.

Response to Arguments

Applicant's arguments, filed 2-3-05, with respect to the rejection of claim 1-20 have been fully considered and the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as follows:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Claims 1-3 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,528,283 to Lang et al (Lang).

Lang discloses cosmetic compositions comprising chitosan as an active agent. Lang discloses that the chitosan compounds of the composition are soluble in water (col. 6, line 23-28). The composition is in the form of a skin cream (a semi-solid) and comprising 0.3% chitosan, Vaseline, which Vaseline reads on barrier protectant, and sodium cetearyl sulfate that reads on instant release agent. The claimed property of solubility is inherent to chitosan of Lang. Example 6 also recites lactic acid that reads on a pH control agent. Thus, Lang anticipates instant claims.

Claims 1-3 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,562,802 to Johansson et al (Johansson).

Johansson discloses topical active barrier cream compositions in the form of gel comprising chitosan, urea, lactic acid, glycerol, cetylstearyl alcohol, paraffin liquid, polyoxyethylene-2-stearyl-ether and saline (col. 16, lines 64-67; example I in col. 17). The components urea, lactic acid, paraffin liquid and polyoxyethylene-2-stearyl-ether read on the claimed skin protectant, pH control agent, and barrier protectant and release agent respectively. The claimed property of solubility is inherent to chitosan of Johansson. Therefore, Johansson anticipates instant claims.

Claim Rejections - 35 USC § 103

Claims 3-9 and 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,562,801 to Johansson et al (Johansson) in view of US 5,614,178 to Bloom et al (Bloom) or alternatively over Johansson and Bloom in view of EP 297 828 (EP).

Johansson discussed above teaches skin composition containing chitosan in the form of cream. Johansson fails to teach the claimed release agent with the claimed HLB value, specific nonionic surfactants, and the additional skin care active agents.

Bloom teaches compositions for topical application containing a high molecular weight polymer, a non-ionic surfactant having a high HLB (above 6) for enhanced penetration of through skin (See col. 3, lines 7-16). Bloom teaches the composition in the form of cream (col. 14, last line). Bloom teaches a number of drugs or active agents, that are water –soluble, including ascorbic acid i.e., vitamin C (col. 9, lines 42, col. 4,

Art Unit: 1615

lines 56-68; cols. 5-9), non-ionic surfactants with HLB above 3 (col. 11, lines 48 through col. 12), which includes the surfactants of instant claims 7-9. Bloom teaches humectants, fatty alcohols and other ingredients in col. 14 and also in examples. The lotions and creams of Bloom (col. 14, last line) read on semi-solid composition of the instant composition. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the non-ionic surfactants (having the claimed HLB value) of Bloom in the topical composition of the Johansson containing chitosan and other active agents because Bloom teaches that topical administration of active agents using the claimed surfactants as penetration enhancing agents (release agents) to administer the active agents in both low and high amounts. Thus, both Bloom and Johansson are directed to topical application of skin treating agents and accordingly a skilled artisan would have expected to achieve an effective transdermal penetration of the chitosan containing composition of Johansson, even in low amounts. Neither Bloom nor Johansson explicitly state "an article". However, it would have been obvious for a skilled artisan at the time of the instant invention to pack the cream composition of Johansson or Bloom, in appropriate dispensers (such as tubes or pumps) so as to effectively deliver the composition.

Alternatively, EP teaches a medicated dressing or bandage for topical application of bioactive agents in the form of a fabric or a pad and is coated or impregnated with the active ingredient in a soft or waxy vehicle, such that the active is released to the skin. The vehicle of EP comprises natural wax, petrolatum or other synthetic waxes; and the

Art Unit: 1615

active agent may an antibacterial or anti-inflammatory agent or anesthetic (page 3).

The bandage of EP is made of a nonwoven or woven fabric (page 3).

Accordingly, it would have been obvious for a skilled artisan at the time of the instant invention to employ a pad, bandage or other appropriate means to apply the composition of Johansson (containing the release surfactants of Bloom) because EP suggests that topical delivery of medicaments can be targeted precisely to the desired location and an efficient release of the active agents through the skin occurs upon local application and at the same time provides a sterile covering over the area of application.

Applicants stated in their response that a terminal disclaimer would be filed upon finding an allowable subject matter. Since no claim is allowed at this time, the following double patenting rejection is maintained:

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,716,441. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims directed to an article and a method of effectively delivering one or more skin care actives recite specific active agents and release agents, which are encompassed by the broadly recited release agents and skin care actives of the instant claims. The specific release composition of the patented claims anticipates the broad genus claimed in the instant invention.

Art Unit: 1615

Examiner notes that claim 13 recites protein hydrolysate is misspelled and a correction is requested.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615

May 17, 2005